

Position Statement on Mid-Urethral Slings for Stress Urinary Incontinence

The International Urogynecological Association (IUGA) supports the use of mid-urethral slings (MUS) as one of the options for the surgical management of female stress urinary incontinence (SUI) which is the type of urinary leakage associated with physical exertion and coughing, laughing, exercise.

Stress urinary incontinence is a common¹, burdensome and costly condition for women with a negative impact on quality of life. Non-surgical measures such as pelvic floor muscle training (PFMT) are useful treatment options in alleviating symptoms although many women proceed with surgery if these are not successful. Surgery is generally a more effective treatment for severe SUI than PFMT.²

Mid-urethral slings are minimally invasive procedures developed in Europe in the 1990s to treat female stress urinary incontinence. These slings are narrow, synthetic polypropylene tapes that are surgically placed beneath the middle part of the urethra (water pipe) to provide dynamic support to stop leakage from the bladder. They have been shown to be as effective as more invasive traditional surgery with major advantages of shorter operating and admission times, and a quicker return to normal activities together with lower rates of complications. This has resulted in MUS becoming the operation of choice in Europe, Asia, South America, South Africa, Australasia and North America for treatment of SUI with several million procedures performed worldwide.

The US Food and Drug Administration (FDA) in the USA released a white paper⁶ and safety communications⁷ regarding safety and effectiveness of transvaginal placement of surgical mesh specifically for pelvic organ prolapse. This is a condition in which some of the pelvic organs bulge downwards giving rise to symptoms. Media attention⁸ on this totally distinct and separate issue of mesh use in women has the potential to cause unnecessary confusion and fear in women considering MUS for treatment of stress urinary incontinence. The FDA publications clearly state that MUS (both retropubic and transobturator slings) were not the subject of their safety communication but further follow-up studies were required for single incision slings.

There is robust evidence⁹⁻¹¹ to support the use of MUS from over 2,000 publications making this treatment the most extensively reviewed and evaluated procedure for female stress urinary incontinence now in use. These scientific publications studied all types of patients, including those with co-morbidities such as prolapse, obesity and other types of bladder dysfunction. It is, however, acknowledged that any operation can cause complications. For MUS these include bleeding, damage to the bladder and bowel, voiding difficulty, tape exposure and pelvic pain; all of these may require repeat surgery but this is uncommon.¹² Nevertheless, the results of a recent large multi-centre trial¹³ have confirmed excellent outcomes and a low rate of complications to be expected after treatment with MUS. Additionally, long term effectiveness of up to 80% has been demonstrated in studies including one which has followed up a small group of patients for 17 years.¹⁴⁻¹⁵

As a result, IUGA supports the use of monofilament polypropylene mid-urethral slings for the surgical treatment of female stress urinary incontinence.

EXHIBIT

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References

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